

REMARKS

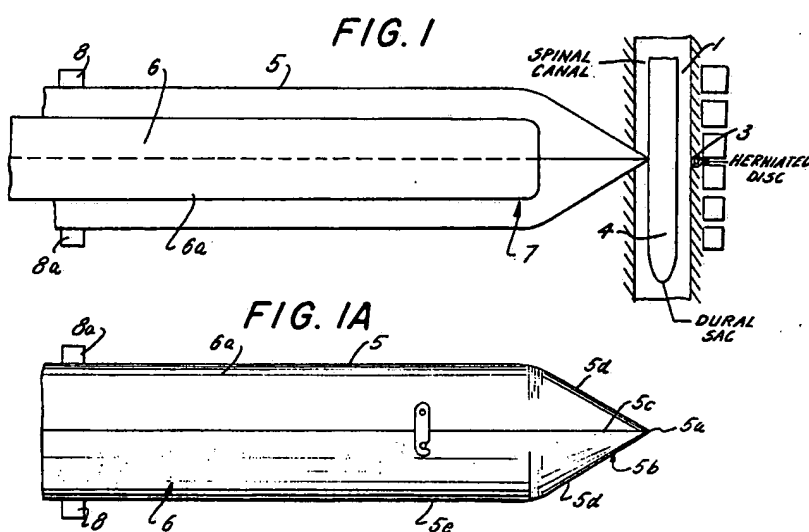
The above-identified application has been reviewed in light of the Office Action mailed March 3, 2006. By the present amendment, the Applicant has amended claim 15. It is respectfully submitted that the claims pending in the application do not introduce new subject matter, are fully supported by the specification, and are patentable over the cited prior art. Prompt and favorable consideration of these claims is earnestly sought.

The Office Action rejected claims 15-20 under 35 U.S.C. § 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over U.S. Patent No. 3,417,745 to Sheldon (the '745 patent). The Office Action characterized the '745 patent as disclosing a shaft, an inflatable bladder which has an eccentric shape upon inflation, and a cannula. The Office Action asserted that the inflatable bladder has the shape of a wedge since it tapers in the proximal direction and is inherently capable of separating adjacent layers of tissue since it is made from Mylar and inflated with a substantially non-compressible fluid.

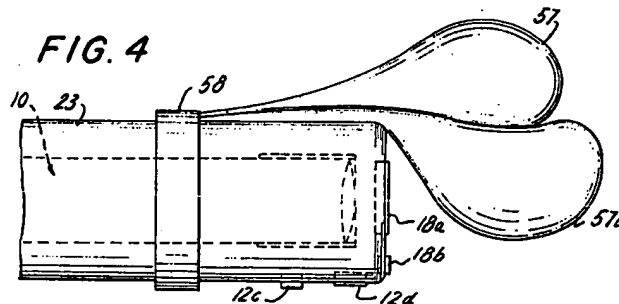
As presently amended, claim 15 recites a device including, *inter alia*, a shaft, an inflatable bladder, and a cannula having "an opening at a proximal end portion, an opening at a distal end portion, and defining a passage therethrough, the passage configured to receive the shaft and deploy the bladder at a target site in tissue."

Contrary to the position taken in the Office Action, the '745 patent does not disclose a cannula; the '745 patent, as shown below in Figures 1 and 1A, discloses a needle 5 with an open proximal end and a **closed distal end**. Specifically, the '745 patent discloses (see Column 3, lines 6 and 7) that the "shaft 5e of the needle terminates a few millimeters before the distal point of the needle 5a." Thus, the '745 patent discloses a needle having a closed distal end that terminates in a point. This construction is necessary for the proper functioning of the disclosed

device. According to the '745 patent disclosure (see Column 9, lines 32-34), "the needle 5 has to penetrate into the spinal sac by puncturing the dura and entering the subarachnoid space." In support of puncturing the dura, the disclosed device requires a distal point. A device having an open end would not puncture the dura and would be incapable of performing the intended function of the disclosed needle.



the recitation of claim 15.



Therefore, the '745 does not teach or fairly suggest an apparatus including, *inter alia*, a cannula having "an opening at a proximal end portion, an opening at a distal end portion, and defining a passage therethrough, the passage configured to receive the shaft and deploy the bladder at a target site in tissue" as recited in amended claim 15. It is respectfully submitted that amended claim 15 is not anticipated or suggested by the '745 patent and the rejection of the Office Action has been overcome. Claims 16-20 depend directly or indirectly from amended independent claim 15 and it is respectfully submitted that these claims are also allowable over the '745 patent.

In the Office Action, claims 15-20 were rejected under 35 U.S.C. § 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over U.S. Patent No. 3,875,595 to Froning (the '595 patent). The Office Action asserted that the '595 patent discloses a shaft, an inflatable bladder that has an eccentric shape upon inflation, and a cannula. The Applicant respectfully disagrees for the reasons below.

The '595 patent, as illustrated below in Figures 4 and 5, discloses an intervertebral prosthesis and a tube. The prosthesis is disposed on a distal end of a shaft and positioned

between adjacent vertebrae as a replacement for a damaged disc. After the damaged disc is removed, the prosthesis is placed in a desired position and inflated such that it acts as a replacement for the removed disc. According to the '595 patent (see Column 3, lines 33-43), fluid is introduced into the prosthesis 46 to expand it to the condition shown in Figure 5, thereby "filling the void 27." The void 27 is previously defined by the removal of the disc nucleus via chemonucleolysis (col. 2, lines 10-17) or via forceps (Fig. 2; col. 1, lines 54-57). By filling this void 27, however, Froning is entirely silent about separating adjacent layers of tissue when its prosthesis 46 is inflated. In fact, Froning only discloses the use of an instrument (not shown) to spread apart adjacent vertebrae (col. 2, lines 38-47). Pins 33 and 33a are inserted into adjacent vertebra to hold them spread apart.

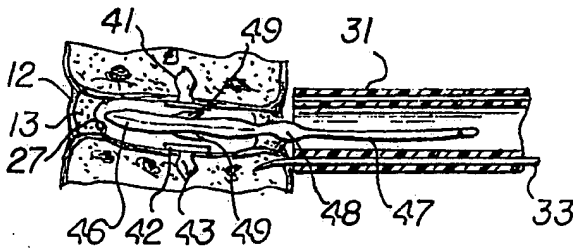


Fig. 4

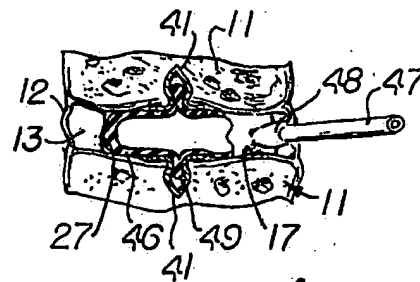


Fig. 5

The Applicant respectfully disagrees with the Examiner's assertion that the inflatable bladder of Froning inherently separates adjacent layers of tissue. As stated in the M.P.E.P. §2112, IV, to establish inherency, the missing descriptive matter must necessarily be present in the reference; here, the Froning inflatable bladder need not separate adjacent layers of tissue because a separate instrument previously separates the tissue to form the "void." Similarly, Froning fails to suggest an inflatable bladder that separates adjacent layers of tissue opposed

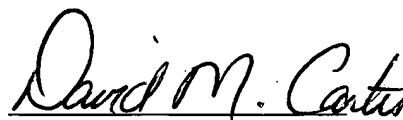
Appl. No. 10/729,768
Amdt. dated June 5, 2006
Reply to Office Action mailed March 3, 2006

surfaces, but instead teaches away from such an inflatable bladder by using a separate instrument for distraction when needed. The Examiner's characterization of the Froning inflatable bladder goes too far; just because an inflatable bladder is inflated with water does not mean that the pressure is sufficient to separate adjacent layers of tissue or that the inflatable bladder can handle such a pressure without rupturing.

Therefore, it is respectfully submitted that amended claim 15 is not anticipated or suggested by the '595 patent and the rejection of the Office Action has been overcome. Claims 16-20 depend directly or indirectly from amended independent claim 15 and it is respectfully submitted that these claims are also allowable over the '595 patent.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in the application, namely claims 15-20, are in condition for allowance. If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call Applicants' undersigned attorney at (631) 501-5713.

Respectfully submitted,



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